

145



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,829	07/14/1999	PATRICK M SCHLIEVERT	600.347USWO	6703
23552	7590	04/13/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/308,829	<b>Applicant(s)</b> SCHLIEVERT ET AL.	
	<b>Examiner</b> Ja-Na Hines	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 45-59,64 and 100-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-59,64 and 100-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment Entry***

1. Amendments have been entered as filed on February 11, 2004. Claims 45-59 and 64 have been amended. Claims 1-44, 60-63 and 65-99 have been cancelled. Claims 100-104 have been newly added. Claims 45-59, 64 and 100-104 are under consideration in this office action.

### **Withdrawal of Rejections**

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The written description rejection of claims 24-27, 35-37 and 45-99 under 35 U.S.C. 112, first paragraph; and

b) The rejection of claims 24-26, 35-37 and 59 under 35 U.S.C. 112, second paragraph.

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 45-59, 64 and 100-104 have been considered but are moot in view of the new ground(s) of rejection.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 45-59, 64 and 100-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-34 and 39 of copending Allowed Application No. 09/336,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/308,829 are drawn to a composition comprising an isolated Streptococcal pyrogenic exotoxin type C (SPE-C toxin) comprising an amino acid substitution at amino acid positions 12, 15, 17, 35 or 38 and specifically referring to substitutions at aspartic acid-12 for alanine; tyrosine-15 for serine; tyrosine-17; histidine-35 for alanine; asparagine-38 for aspartic acid or serine all within SEQ ID NO:2 and carrier.

The claims of 09/336,036 are drawn to an isolated Streptococcal pyrogenic exotoxin type C (SPE-C toxin) comprising amino acid substitution at amino acid positions 12, 15, 17, 35 or 38 and specifically referring to substitutions at aspartic acid-12 for alanine; tyrosine-15 for serine; tyrosine-17; histidine-35 for alanine; asparagine-38 for aspartic acid or serine all within of SEQ ID NO:2.

The claims 09/308,829 and 09/336,036 are both drawn the same isolated Streptococcal pyrogenic exotoxin type C (SPE-C toxin) comprising amino acid substitution at the same amino acid positions 12, 15, 17, 35 or 38 referring to the same amino acid sequence. Thus, the isolated Streptococcal pyrogenic exotoxin type C (SPE-C toxin) comprising amino acid substitution at amino acid positions 12, 15, 17, 35 or 38 are not patentably distinct even though one is comprised in a compositions with a carrier. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented but have been allowed.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1645

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *JNA*  
April 6, 2004

*L. F. Smith*  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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